

Remarks:

Claims 1-14 and 20-21 remain for consideration in this application along with newly added claim 22. Claims 15-19 have been canceled. In light of the above amendments and the remarks hereunder the rejections of the last office action are respectfully traversed.

The invention generally concerns a machine readable assaying arrangement and a method for drug screening an individual. The arrangement comprises a substrate providing at least one assaying indicia on the surface thereof having an initial encoded value. The assaying indicia is capable of changing to a second encoded value upon detection of a desired state. One preferred embodiment of the invention is useful for confidentially drug screening an individual. In this preferred embodiment, the substrate is adapted to be contacted with a urine sample from the individual and the assaying indicia is capable of changing from a first encoded value to a second encoded value in response to contact with the urine sample. The assaying indicia is machine readable and not interpretable by the tested individual or others viewing the assaying indicia.

In the office action, the Examiner rejected claims 1-21 as being based upon a defective reissue declaration under 35 U.S.C. 251 because the declaration fails to identify at least one error which is relied upon in support of the reissue application. However, it is the Applicant's position that the reissue declaration filed does identify at least one error which provides grounds for reissue of the patent. The reissue declaration states (bottom of page 1 of 2) that, "The claims as patented are not specific to assaying apparatus and methods for drug screening of an individual." In essence, the declaration is stating that the patented claims are not narrowly tailored to an apparatus and methods for drug screening an individual. Furthermore, the original patent did not contain any claims specifically directed towards a method; this is one error for which reissue is sought. MPEP 1414 states that MPEP 1402 contains grounds for filing a reissue that may constitute the "error"

required by 35 U.S.C. 251. One of these grounds listed in MPEP 1402 is that the claims are too narrow or too broad. Applicant submits that the error upon which reissue is based as given in the reissue declaration sufficiently falls under the grounds set forth in MPEP 1402. Therefore, the rejection based on a defective reissue declaration should be withdrawn.

The Examiner questioned the preliminary amendment updating the continuity of the parent application referred to in column 1, line 7 of the specification. As originally filed, this application stated that it was a continuation of copending application S/N 08/832,957. This statement is incorrect. The application is in fact a continuation-in-part of the '957 application. This fact is apparent from a side-by-side comparison of both the present application and the '957 application which issued as U.S. Patent No. 5,929,422, on July 27, 1999. While there is overlapping subject matter, it is plain to see that the current application contains figures and descriptions not present in the '957 application. Therefore, the preliminary amendment properly corrects the error contained in the original specification by changing this application's status from a continuation to a CIP.

The Examiner objected to the drawings in that the "method steps of claims 20 and 21" are not shown. Applicant has added Figure 7, along with a brief description, in order to overcome this deficiency. No new matter has been added as this subject matter is fully supported by the specification as originally filed in col. 8, ll. 44-67. Therefore, Applicant requests that the objection to the drawings be withdrawn.

The Examiner rejected claims 15-21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Particularly, the Examiner was unclear as to how the applicant can have indicia that is not "human readable" with the system that is disclosed. Applicant has amended claim 20 by replacing the "human readable" limitation with the limitation that the assaying

indicia be "machine readable only and not human interpretable in the absence of said machine reading." This amendment distinguishes between mere visual detection by a human of the changes the indicia undergoes and the indicia not being human interpretable in the absence of machine reading. By not being directly discernable to the individual being tested or others viewing the indicia, the results of the drug screening remain confidential. The amendment to claim 20 is fully supported by the specification in col. 1, ll. 61. As noted above, claim 15 has been canceled. In light of the amendment to claim 20, the §112, second paragraph rejection should be withdrawn.

The Examiner rejected claims 15 and 17-21 under 35 U.S.C. 103(a) as being unpatentable over Hochstrasser (U.S. Patent Nos. 4,042,329 and 4,059,407). As previously stated, claims 15-19 have been canceled. Claim 20 has been amended to include the limitation that the assaying indicia includes one analysis element, one fixed element and a blank space in between. In stating the reasons for the indication of allowable subject matter on page 7 of the office action, the Examiner notes that the prior art references fail to teach or suggest that the indicia includes at least one analysis element, at least one fixed element and at least one blank region therebetween. Therefore, because claim 20 now includes this limitation, which the Examiner states is the basis for allowance of claims 1-10, the §103(a) rejection as to claims 20-21 should be withdrawn.

The Examiner has indicated that claims 1-14 are allowable over the prior art of record. The Examiner also indicated that claim 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and to include all of the limitations of the base claim and any intervening claims. Claim 16 has been rewritten in independent form as new claim 22. Applicant has incorporated into claim 22 the same language used to overcome the §112, second paragraph rejection of claim 20. Therefore, the §112, second paragraph deficiency of claim 16 has been overcome and claim 22 is in condition for allowance.

Finally, the Examiner rejected claims 15 and 17-21 under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. As claims 15 and 17-19 have been canceled and claims 20-21 amended to include the limitation of an analysis element, a fixed element and blank space therebetween, the recapture rejection is now moot.

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,

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ATTORNEYS FOR APPLICANT(S)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Drawings:

Entry of Figure 7 was requested.

Specification:

Please add the following paragraph at column 2, line 68, following the description of Fig. 6:

FIG. 7 illustrates a method of drug screening an individual in accordance with one embodiment of the invention.

Claims:

The following claim was amended:

20. A method of drug screening an individual, comprising the steps of:

obtaining a urine sample from said individual;

providing an assay member supporting a substrate having a surface adapted to be contacted
with said urine sample;

at least one [of] assaying indicia provided upon said surface and having an initial encoded
value, said indicia capable of changing to a second encoded value in response to said
contact with said sample,

said assaying indicia including at least one analysis element, at least one fixed element, and
at least one blank region therebetween and being machine readable only and not
human [readable] interpretable in the absence of said machine reading, so that others
viewing said indicia after said contact with said sample are unable to directly
interpret the results of the individual's drug screening assay without said machine

reading;

machine reading said assaying indicia after said urine contacting step to ascertain the drug

screen results; and

storing said drug results in electronic memory.

Claim 22 was added.

Claims 15-19 were canceled.